

Appl. No. 09/177,711  
Amdt. dated October 21, 2003  
Amendment under 37 CFR 1.116 Expedited Procedure  
Examining Group

PATENT

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-59 (canceled)

Claim 60 (currently amended): A method of decreasing pain associated with use of prostaglandins for treatment of erectile tissue dysfunction comprising administering to a human subject in need thereof an effective amount of prostaglandin and at least one NO producing agent at a low dose, ~~which does not produce significant systemic side effects, but~~ which decreases pain associated with prostaglandin use, wherein said low dose of said at least one NO producing agent is a unit dose of about 0.88  $\mu$ mole or less, and wherein the administration is therapeutically synergistic in the treatment of erectile tissue dysfunction, and is not an intraurethral administration.

Claim 61 (currently amended): The method of claim 60 wherein the subject human is male.

Claim 62 (currently amended): The method of claim 60 wherein the subject human is female.

Claim 63 (canceled).

Claim 64 (previously presented): The method of claim 60 wherein the NO producing agent inhibits a cyclic nucleotide phosphodiesterase.

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Claim 65 (previously presented): The method of claim 64 wherein the cyclic nucleotide phosphodiesterase is PDE3.

Claim 66 (currently amended): The method of claim 60 wherein the NO producing agent is delivered by a route selected from the group consisting of oral administration, intravenous administration, subcutaneous administration, inhalation or intranasal administration, transdermal application, topical application, rectal administration, ~~intraurethral administration~~, and intracavernous introduction.

Claim 67 (previously presented): The method of claim 60 wherein two agents are administered.

Claim 68 (previously presented): The method of claim 60 wherein the NO producing agent is selected from the group consisting of glyceryl trinitrate, isosorbide 5-mononitrate, isosorbide dinitrate, pentaerythritol tetranitrate, erythrityl tetranitrate, sodium nitroprusside, 3-morpholiniosydnonimine, molsidomine, S-nitroso-N-acetylpenicillamine, S-nitrosoglutathione, N-hydroxy-L-arginine, S,S-dinitrosodithiol and NO gas.

Claim 69 (previously presented): The method of claim 60 wherein the NO producing agent is glyceryl trinitrate.

Claim 70-111 (canceled)

Claim 112 (new): The method of claim 66 wherein the NO producing agent is delivered by inhalation.

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Claim 113 (new): The method of claim 66 wherein the NO producing agent is delivered by transdermal application.

Claim 114 (new): The method of claim 66 wherein the NO producing agent is delivered by oral administration.

Claim 115 (new): The method of claim 60 wherein said NO producing agent augments the action of cGMP.

Claim 116 (new): The method of claim 60 wherein said NO agent is sodium nitroprusside and said effective amount of prostaglandin is an effective amount of prostaglandin E1.

Claim 117 (new): The method of claim 60 wherein said at least one NO producing agent is a unit dose of 200  $\mu$ g or less.

Claim 118 (new): The method of claim 60 wherein the mole ratio of said effective amount of prostaglandin to said at least one NO producing agent is about 1 to 12.

Claim 119 (new): The method of claim 60 wherein the mole ratio of said effective amount of prostaglandin to said at least one NO producing agent is about 1 to 4.

Claim 120 (new): The method of claim 60 wherein the mole ratio of said effective amount of prostaglandin to said at least one NO producing agent is about 1 to 3.

Claim 121 (new): The method of claim 116 wherein said sodium nitroprusside administered is about 50  $\mu$ g and said effective amount of prostaglandin (PGE1) administered is about 5-20  $\mu$ g.

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Claim 122 (new): The method of claim 66 wherein said NO producing agent is delivered by intracavernous administration.